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MCDERMOTT, WILL & EMERY

August 5, 2002

VIA HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852

Re: Star Scientific, Inc.'s Filing of Response to Campaign for Tobacco-Free Kids
Concerning Citizen Petition, Docket No. 01P-0572

Dear Sir/Madam:

On behalf of our client, Star Scientific, Inc., attached please find the response to comments by the Campaign for Tobacco-Free Kids ("CTFK") on the Citizen Petition referenced above filed concerning Star Scientific's smokeless compressed tobacco product, Ariva™ Cigalett™ pieces.

The CTFK's comments do not contribute any new information concerning the legal question of whether the Food and Drug Administration ("FDA") has the authority to regulate Ariva™ as a "drug" or "food" under the Federal Food, Drug and Cosmetic Act ("FDCA.") Further, as our attached response demonstrates, the CTFK's comments both ignore important facts and wrongly imply that Ariva is being improperly marketed when, in reality, retailers have been legally and appropriately selling Ariva in the same manner as other tobacco products. The CTFK's comments should therefore not be accorded any weight in considering the above referenced Citizen Petition.

We maintain the firm belief that Star Scientific's smokeless compressed tobacco product Ariva™ falls outside of FDA's jurisdiction pursuant to the Supreme Court decision in *FDA v. Brown & Williamson Tobacco Corporation*, 529 U.S. 120 (2000) and that the Petition is without merit and should be denied.

Sincerely yours,



David L. Rosen

OIP-0572

RC3

cc: Charles Fried, Esq.

Paul L. Perito, Esq.
Chairman, President and COO
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Robert E. Pokusa, Esq.
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